DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration
Minneapolis District Office
Central Region
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Minneapolis, MN 55401
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June 24, 2004

WARNING LETTER

VIA CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 04 - 29

American Sports Nutrition
2551 45th Street SW, Suite D
Fargo, North Dakota 58104

Dear Sir or Madam:

This letter is in reference to your firm's marketing and distribution of ASN Canthaxanthin capsules. The Food and Drug Administration (FDA) has reviewed your web site at the following address: *www.xlr8sportsnutrition.com.* This review shows serious violations of the Federal Food, Drug, and Cosmetic Act (the Act) in the labeling of your product. You can find the Act and implementing regulations through links on FDA's Internet home page at *www.fda.gov.*

Under the Act, articles intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in man are drugs [Section 201(g)(1)(B) of the Act]. Articles other than food that are intended to affect the structure or any function of the body of man are also drugs [Section 201(g)(1)(C) of the Act]. Your web site claims that your product ASN Canthaxanthin is useful in the prevention of sun damage, genetic damage, and skin cancer. The Internet labeling of your product bears the following claims:

- "The use of Canthaxanthin may decrease one's chances of getting skin cancer ... by preventing sun damage to the skin."
- "Carotenoids also protect plants from direct ultra violet damage by absorbing ... ultra violet photons.... Like wise [sic], in animals, protecting DHA [sic] from genetic damage. ... Canthaxanthin is a naturally occurring carotenoid found in many different plants and animals."
- "Canthaxanthin functions as a [sic] ultra violet photon absorber...."

These claims cause your product to be a drug as defined in sections 201(g)(1)(B) and 201(g)(1)(C) of the Act. Because this product is not generally recognized as safe and effective when used as labeled, it is also a new drug as defined in section 201(p) of the Act. Under section 505 of the Act, a new drug may not be legally marketed in the United States without an approved New Drug Application (NDA).

Even if the labeling for this product did not contain claims which cause it to be a drug, this product is an adulterated cosmetic. Your Internet web site promotes this product for coloring the skin. The Act defines the term "cosmetic" at section 201(i)(1) to include articles intended to be introduced into the human body for altering the appearance. The following web site statements establish that this Canthaxanthin product is intended for use to alter the skin color to simulate a suntan:

- "[T]he Canthaxanthin molecules attaches [sic] to the subcutaneous layer of fat cells (insulin fat) that is directly under the skin. Since the skin is translucent the fat that has been darken [sic] by the Canthaxanthin shows through."
- "Saturation is achieved when the entire body has obtained an orange/bronze color easily detected in the face, hands, and feet."
- "Once the saturation point has been achieved, cut the dosage in half. You can then regulate the coloring by taking more of [sic] less capsules on a daily basis."
- "It takes about 3-4 wks. after saturation before the bronze coloring is achieved."

The above claims establish that the Canthaxanthin product you are currently marketing on your web site is intended to impart color to the skin, thus making it a cosmetic product.

The Act defines the term "color additive" at section 201(t)(1)(B) as a material which, when added or applied to a food, drug, or cosmetic, or to the human body or any part thereof, is capable (alone or through reaction with another substance) of imparting color thereto. Canthaxanthin is a color additive. Color additives are deemed to be unsafe unless they are used in accordance with a color additive regulation that specifies the conditions under which the color additive may be safely used, including the purposes for which it may be used and the product category or categories to which it may be added [Section 721(a) of the Act]. There is no color additive regulation currently allowing for the use of canthaxanthin to impart color to the skin or, for that matter, for the use of canthaxanthin in a cosmetic product for any purpose.

Based on the above, the ASN Canthaxanthin product you are marketing on your web site is adulterated under section 601(e) of the Act, in that it bears or contains a color additive, namely canthaxanthin, which is unsafe within the meaning of section 721(a) of the Act. It is a violation of section 301(a) of the Act to introduce or deliver for introduction into interstate commerce any cosmetic that is adulterated.

This letter is not intended to be an all inclusive review of your products and labeling. It is your responsibility to ensure that all products marketed by your firm are in compliance with the Act and its implementing regulations.

We request that you take prompt action to correct these violations. Failure to promptly correct these violations may result in enforcement action being initiated by the Food and Drug Administration without further notice. The Act provides for the seizure of illegal products and for injunction against the manufacturer and/or distributor of illegal products.

Please notify this office in writing within fifteen (15) working days of the receipt of this letter as to the specific steps you have taken to correct the stated violations, including an explanation of each step being taken to identify and make corrections to assure that similar violations will not recur. If the corrective action cannot be completed within 15 working days, state the reason for the delay and the time frame within which the corrections will be implemented.

Your reply should be sent to the Food and Drug Administration, Compliance Officer Brian D. Garthwaite, Ph.D., Minneapolis District Office, 212 Third Avenue South, Minneapolis, Minnesota 55401.

Sincerely,

W. Charles Becoat
Director
Minneapolis District

BDG/ccl
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